

**60th Medical Group (AMC), Travis AFB, CA**  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**  
**FINAL REPORT SUMMARY**

(Please type all information. Use additional pages if necessary.)

**PROTOCOL #:** FDG20150034A

**DATE:** 24 January 2017

**PROTOCOL TITLE:** "Comparison of Temporary Open Arterial Revascularization Using Stent Grafts vs. Standard Vascular Shunts in a Porcine (*Sus scrofa*) Model."

**PRINCIPAL INVESTIGATOR (PI) / TRAINING COORDINATOR (TC):** Capt Anders Davidson

**DEPARTMENT:** SGSE

**PHONE #:** 423-7400

**INITIAL APPROVAL DATE:** 27 August 2015

**LAST TRIENNIAL REVISION DATE:** 25 Aug 16

**FUNDING SOURCE:** SG

**1. RECORD OF ANIMAL USAGE:**

Animal Species:	Total # Approved	# Used this FY	Total # Used to Date
<i>Sus scrofa</i>	20	20	20

**2. PROTOCOL TYPE / CHARACTERISTICS:** (Check all applicable terms in **EACH** column)

<input type="checkbox"/> Training: Live Animal	<input type="checkbox"/> Medical Readiness	<input type="checkbox"/> Prolonged Restraint
<input type="checkbox"/> Training: non-Live Animal	<input type="checkbox"/> Health Promotion	<input type="checkbox"/> Multiple Survival Surgery
<input checked="" type="checkbox"/> Research: Survival (chronic)	<input type="checkbox"/> Prevention	<input type="checkbox"/> Behavioral Study
<input type="checkbox"/> Research: non-Survival (acute)	<input type="checkbox"/> Utilization Mgt.	<input checked="" type="checkbox"/> Adjuvant Use
<input type="checkbox"/> Other (                    )	<input checked="" type="checkbox"/> Other (Treatment )	<input type="checkbox"/> Biohazard

**3. PROTOCOL PAIN CATEGORY (USDA):** (Check applicable) ☐ C ☒ D ☐ E

**4. PROTOCOL STATUS:**

**\*Request Protocol Closure:**

☐ Inactive, protocol never initiated

☐ Inactive, protocol initiated but has not/will not be completed

☒ Completed, all approved procedures/animal uses have been completed

**5. Previous Amendments:**

List all amendments made to the protocol.. **IF none occurred, state NONE. Do not use N/A.**

**For the Entire Study Chronologically**

Amendment Number	Date of Approval	Summary of the Change
1	16 June 2016	Personnel

6. **FUNDING STATUS:** Funding allocated: \$3045.00 Funds remaining: \$

7. **PROTOCOL PERSONNEL CHANGES:**

Have there been any personnel/staffing changes (PI/CI/AI/TC/Instructor) since the last IACUC approval of protocol, or annual review?   X   Yes        No

If yes, complete the following sections (Additions/Deletions). For additions, indicate whether or not the IACUC has approved this addition.

**ADDITIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, IACUC approval - Yes/No)

---

---

**DELETIONS:** (Include Name, Protocol function - PI/CI/AI/TC/Instructor, Effective date of deletion)

Maj Lucas Neff (AI), 16 June 2016

8. **PROBLEMS / ADVERSE EVENTS:** Identify any problems or adverse events that have affected study progress. Itemize adverse events that have led to unanticipated animal illness, distress, injury, or death; and indicate whether or not these events were reported to the IACUC.

Sponge left in the abdomen of one animal leading to some suspected GI distress. This event was reported to the IACUC.

9. **REDUCTION, REFINEMENT, OR REPLACEMENT OF ANIMAL USE:**

**REPLACEMENT (ALTERNATIVES):** Since the last IACUC approval, have alternatives to animal use become available that could be substituted in this protocol without adversely affecting study or training objectives?

No

**REFINEMENT:** Since the last IACUC approval, have any study refinements been implemented to reduce the degree of pain or distress experienced by study animals, or have animals of lower phylogenetic status or sentience been identified as potential study/training models in this protocol?

No

**REDUCTION:** Since the last IACUC approval, have any methods been identified to reduce the number of live animals used in this protocol?

No

10. **PUBLICATIONS / PRESENTATIONS:** (List any scientific publications and/or presentations that have resulted from this protocol. Include pending/scheduled publications or presentations).

To be presented at the Western Trauma Annual Meeting March 5-10 at Snowbird, UT. Planned submission to the Journal of Trauma and Acute Care Surgery

11. **Were the protocol objectives met, and how will the outcome or training benefit the DoD/USAF?**

Yes. Demonstrated improved hemodynamics of stent grafts when compared to temporary vascular shunts.

12. **PROTOCOL OUTCOME SUMMARY:** (Please provide, in "ABSTRACT" format, a summary of the protocol objectives, materials and methods, results - include tables/figures, and conclusions/applications.)

**Objectives:** Open surgical reconstruction using expanded polytetrafluoroethylene stent grafts to create a "sutureless" anastomosis is an alternative to standard temporary vascular shunts. We sought to characterize patency and flow characteristics of these grafts compared to standard shunts in a survival model of porcine vascular injury.

**Methods:** 12 Yorkshire-cross swine received a 2cm long near-circumferential defect in the iliac arteries. A14-French Argyle shunt was inserted into one randomly assigned artery, with a self-expanding ePTFE stent deployed in the other. Arterial flow measurements were obtained at baseline, immediately after intervention, and after 72 hours. Blood pressure proximal and distal to the conduits and arterial samples for histopathology were obtained during the terminal procedure.

**Results:** Angiography revealed no difference in patency at 72 hours. The stent grafts demonstrated significantly improved blood flow compared to shunts both immediately after intervention and at 72 hours. The pressure gradient across the shunts was greater than that of the stent grafts.

**Conclusion:** Open "sutureless" direct site repair using stent grafts to treat vascular injury is a feasible strategy for damage control management of peripheral vascular injury and offers increased blood flow when compared to temporary shunts. Furthermore, stent grafts may offer improved durability to extend the window until definitive vascular repair



---

(PI / TC Signature)

26-Jan-17  
(Date)

**Attachments:**

Attachment 1: Defense Technical Information Center (DTIC) Abstract Submission **(Mandatory)**

**Attachment 1****Defense Technical Information Center (DTIC) Abstract Submission**

**This abstract requires a brief (no more than 200 words) factual summary of the most significant information in the following format: Objectives, Methods, Results, and Conclusion.**

**Objectives:** Open surgical reconstruction using expanded polytetrafluoroethylene stent grafts to create a “sutureless” anastomosis is an alternative to standard temporary vascular shunts. We sought to characterize patency and flow characteristics of these grafts compared to standard shunts in a survival model of porcine vascular injury.

**Methods:** 12 Yorkshire-cross swine received a 2cm long near-circumferential defect in the iliac arteries. A 14-French Argyle shunt was inserted into one randomly assigned artery, with a self-expanding ePTFE stent deployed in the other. Arterial flow measurements were obtained at baseline, immediately after intervention, and after 72 hours. Blood pressure proximal and distal to the conduits and arterial samples for histopathology were obtained during the terminal procedure.

**Results:** Angiography revealed no difference in patency at 72 hours. The stent grafts demonstrated significantly improved blood flow compared to shunts both immediately after intervention and at 72 hours. The pressure gradient across the shunts was greater than that of the stent grafts.

**Conclusion:** Open “sutureless” direct site repair using stent grafts to treat vascular injury is a feasible strategy for damage control management of peripheral vascular injury and offers increased blood flow when compared to temporary shunts. Furthermore, stent grafts may offer improved durability to extend the window until definitive vascular repair.

**Grant Number:** \_\_\_\_\_

**From:** \_\_\_\_\_

**\*\*If you utilized an external grant, please provide Grant # and where the grant came from. Thank you.**